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MAIL STOP - PCT

Attorney Docket No.: 27129U

Date: 6 July 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SHARIM

Art Unit: Unknown

Examiner: Unknown

Application No.: 10/560,901

Filed: 16 December 2005

International Application No.: PCT/IL2004/000524

International Filing Date: 17 June 2004

Title: **ORTHOPEDIC CLAMPS**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

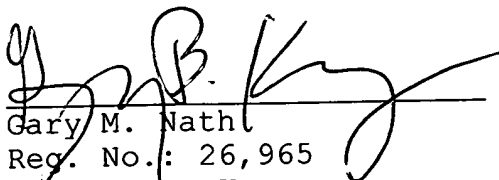
Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Submission of Documents to Supplement Filing Documents under 35 USC 371;
- 2) PCT/IB/373 (International Preliminary Report on Patentability);
- 3) PCT/ISA/237 (Written Opinion of the International Searching Authority).

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC

By:


Gary M. Nath

Reg. No.: 26,965

Gregory B. Kang

Reg. No.: 45,273

Customer No.: 20529



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SUBMISSION OF DOCUMENTS

TO SUPPLEMENT FILING DOCUMENTS UNDER 35 USC 371

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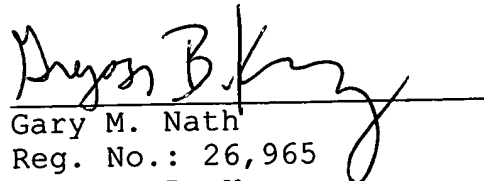
In order to supplement the filing documents for the national phase filing Under USC 371 commenced on **16 DECEMBER 2005**, applicant now submits the following documents:

- 1) PCT/IB/373 (International Preliminary Report on Patentability);
- 2) PCT/ISA/237 (Written Opinion of the International Searching Authority).

Please charge any deficiency or credit any overpayment to our Deposit Account Number 14-0112.

Respectfully submitted,
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PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 151855 4 IL	FOR FURTHER ACTION		See item 4 below
International application No PCT/IL2004/000524	International filing date (<i>day/month/year</i>) 17 June 2004 (17.06.2004)	Priority date (<i>day/month/year</i>) 17 June 2003 (17.06.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant FACET-MED LTD.			

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1	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a)		
2	This REPORT consists of a total of 9 sheets, including this cover sheet		
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.		
3.	This report contains indications relating to the following items:		
	<input checked="" type="checkbox"/> Box No. I	Basis of the report	
	<input checked="" type="checkbox"/> Box No. II	Priority	
	<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	
	<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention	
	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
	<input type="checkbox"/> Box No. VI	Certain documents cited	
	<input type="checkbox"/> Box No. VII	Certain defects in the international application	
	<input type="checkbox"/> Box No. VIII	Certain observations on the international application	
4	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis 3(c) and 93bis 1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis 2)		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No +41 22 740 14 35	Date of issuance of this report 19 December 2005 (19.12.2005)
	Authorized officer Simin Baharlou Telephone No. +41 22 338 71 30

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 08 FEB 2005

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To:

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see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IL2004/000524

International filing date (day/month/year)
17.06.2004

Priority date (day/month/year)
17.06.2003

International Patent Classification (IPC) or both national classification and IPC
A61B17/70, A61B17/80

Applicant
SHARIM, Hamid

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2 **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66 1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3 For further details, see notes to Form PCT/ISA/220

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Compos, F

Telephone No +31 70 340-1957



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No
PCT/IL2004/000524

Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/000524

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 8-18

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because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 8-18
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☒ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

- ☐ paid additional fees
- ☐ paid additional fees under protest.
- ☒ not paid additional fees.

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2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. ~~This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is~~

- ☐ complied with
- ☒ not complied with for the following reasons:

see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts
- ☒ the parts relating to claims Nos. 1-7

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-7
	No: Claims	1-4
Inventive step (IS)	Yes: Claims	5-7
	No: Claims	1-4
Industrial applicability (IA)	Yes: Claims	1-7
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Claims 10-18: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.

Claims 8,9: Seem item IV below.

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Re Item IV.

The separate inventions are:

Claims 1-7: Saddle clamp shaped to fit over the inferior and superior articular processes of successive vertebrae

Claims 1,8,9: Clamp of arcuate shape for fixation to tubular bones.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The features of claims 1-4 are well known in the field of the fixation or fusion of bones in general, as can be readily seen in US645131, US5387212, and US5582612. The content of these claims can therefore not be used to define a common technical concept for the remaining dependent claims. The remaining claims can be grouped as follows, with respect to the features they contain:

Claims 5-7: Saddle clamp for fixation to vertebrae, said clamp being shaped to straddle the superior articular facet.

Claims 8,9: Clamp of arcuate shape for fixation to tubular bones.

The above two groups of claims have features which make them adaptable only to particular types of bones, these two groups of claims therefore aim to provide different solutions to different problems.

The application therefore relates to a plurality of inventions, or groups of inventions, in the sense of Rule 13.1 PCT.

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Re Item V.

1. The following document is referred to in this communication:

D1: US-B-6 458 1311 (RAY R CHARLES) 1 October 2002 (2002-10-01)

D2: US-A-5 387 212 (YUAN HANSEN A ET AL) 7 February 1995 (1995-02-07)

D3: US-A-5 582 612 (LIN CHIH-I) 10 December 1996 (1996-12-10)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Figure 7 of D1 discloses a clamp for mounting to the curved surface of a bone, for carrying a bone fixing member, said clamp having a rigid body (700) and at least two holes (706/708) for passing fixing elements and at least one assembly element integral with said body for attaching said bone fixing member.

3. Dependent claims 2-4 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

Claim 2: D2, figure 2a.

Claims 3,4: D1, figures 3, 4, and 7

4. The features of claim 5 are not found in the available prior art. The subject-matter of claim 5 is therefore novel (Article 33(2) PCT). Claim 6 and 7 are dependent on claim 5 and therefore also novel.

The special saddle shape of the clamp as disclosed in claim 5, which closely conforms to the pedicle and superior articular facet of a vertebra, together with screw holes placed as they are, have the advantage of being able to firmly fix the clamp to a part of the vertebral anatomy which is far removed from the spinal cord. This makes for a much safer procedure compared to those which have to rely on screws or hooks to be placed into the vertebral body or around the spinal process as in D1-D3, these require drilling or manipulation of hooks extremely close to the spinal cord. The subject-matter of claim 5 therefore also involves an inventive step (Article 33(3) PCT).

PCT/IL2004/000524

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